

Application No. : 09/815,982
Filed : March 22, 2001

REMARKS

Claims 1-8, 10-14, 19-24, 36, 38 and 41-58 were pending in the application. By this paper, Applicant has amended Claims 1, 19, 46 and 51. Accordingly, Claims 1-8, 10-14, 19-24, 36, 38 and 41-58 are presented herein for examination.

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§102 Rejections

Claim 1 – In response to the Examiner’s Section 102 rejection of Claim 1 over Voss, et al (US 6,228,034, which is commonly owned by the Applicant of the present application, formerly
10 named “Vitalwave Corporation”), Claim 1 has been amended herein to include limitations wherein “said act of identifying comprising automatically detecting a local minimum indicative of both lateral position and depth.” While Applicant believes that Claim 1 distinguishes over the prior art of record as previously presented, Applicant has herein amended Claim 1 to further clarify the subject of Applicant’s invention. Support for this limitation can be found, *inter alia*,
15 at Page 36, lines 15-19 of the present application.

While Voss does allow for the tilt of ultrasonic bursts across a subject’s wrist, it is only looking to detect maximum Doppler signal strength resulting from the detection of maximum blood flow velocity. Voss is not concerned with, nor does it teach or remotely suggest, detecting a local minimum indicative of both lateral position and depth of an artery of interest. In fact,
20 Applicant submits that Voss teaches away from Applicant’s invention of Claim 1, since it states that blood flow detection is the mechanism by which it works (i.e., detection of tissue (e.g., the artery) would provide no relevant information regarding blood flow velocity, such velocity being necessary for the invention of Voss to operate:

25 *“The bursts are scattered by red blood cells flowing through the artery, and the ultrasonic transducer receives back a portion of the scattered bursts. The scattered bursts are Doppler shifted according to the velocity of the blood. The ultrasound system then compares the frequencies and phase angles of the transmitted and returned bursts, and it monitors the magnitude of the comparison
30 signal to determine the proximity of the ultrasonic transducer to the artery.”*

Application No. : 09/815,982
Filed : March 22, 2001

Voss therefore as a matter of law, cannot anticipate Claim 1 of the present invention as amended, since (i) it does not teach detecting a local minimum indicative of both lateral position and depth; and (ii) it teaches away from using reflections from the blood vessel itself.

Moreover, Applicant submits that Voss does not teach or suggest (i) “evaluating reflections of said acoustic energy from said tissue and said blood vessel”, nor (ii) “identifying at least one region of reduced energy reflection within said tissue, said at least one region corresponding to said blood vessel”, as both set forth in Claim 1 herein.

Regarding Item (i), Voss performs no evaluation of energy reflected from the tissue or blood vessel, because its evaluation (as noted in the citation from Voss presented above) comprises comparing “the frequencies and phase angles of the transmitted and returned bursts, and it monitors the magnitude of the comparison signal”. Stated differently, the tissue or artery would produce no comparison signal because it does not move; the change in frequency and/or phase angle is purely an artifact of moving objects (e.g., blood). Hence, even if the signals reflected off the tissue/blood vessel in Voss were received by its transducer, literally no evaluation of these signals would be performed since there is no Doppler component.

Regarding Item (ii), Voss performs no identification of at least one region of reduced reflection within the tissue, for the very same reasons as set forth in item (i) above; i.e., Voss performs no analysis or identification of anything having to do with the tissue (versus the blood) since the tissue produces no Doppler shift. **How could Voss identify a region of reduced reflection as in Claim 1 when it a) has no apparatus to identify a region of reduced reflection associated with anything (tissue or blood), and b) does not “evaluate” non-Doppler signals (i.e., those generated by the tissue)?**

Applicant therefore respectfully submits that Claim 1 as amended distinguishes over Voss on multiple bases, and is in condition for allowance.

Claim 7 – Applicant respectfully disagrees with the Examiner’s contention that Voss et al anticipates Claim 7, and traverses this rejection in its entirety. The Voss reference does not teach or even remotely suggest, *inter alia*, “detecting the location of said at least one wall of the blood vessel.” Voss only teaches using an ultrasonic blood flow sensor to detect blood flow and

Application No. : 09/815,982
Filed : March 22, 2001

perhaps implicitly the blood (i.e., lumen) itself; see discussion and citation above with respect to Claim 1. Voss in no way teaches or suggests that it has the ability to detect the location of the wall of a blood vessel. As Voss does not teach or suggest such functionality, and in fact teaches away from such functionality by requiring that only reflections from the blood cells (blood) be
5 utilized (i.e., only the Doppler-producing objects would generate the “comparison” signal of Voss), it cannot as a matter of law anticipate Claim 7.

Therefore, Applicant respectfully submits that Claim 7 is in condition for allowance as well.

10 **Claim 8** – Applicant respectfully disagrees with the Examiner’s contention that Claim 8 is anticipated by Voss et al, and traverses this rejection as well. Claim 8 discloses, *inter alia*, “correlating said at least one plateau to the location of said blood vessel.” Applicant can find no support for the Examiner’s contention that Voss somehow teaches or suggests identifying any plateau, let alone correlating a plateau to the location of a blood vessel.

15 While Voss monitors the magnitude of the comparison signal in order to determine the proximity of the sensor to the artery, it does not teach or suggest utilizing acoustic wave beams to identify a plateau in backscattered energy. It is only concerned with finding a maximum Doppler signal strength response to help properly position the sensor as close as practicable over the artery. **Applicant requests that the Examiner specifically point to support within the Voss
20 reference that teaches identifying a plateau and correlating the plateau with the location of a blood vessel.**

Because Applicant believes that Voss does not teach each and every limitation of Claim 8, Applicant respectfully submits that Claim 8 distinguishes over the art of record, and is in condition for allowance.

25 **Claim 19** – In response to the Examiner’s Section 102 rejection, Applicant has herein amended Claim 19 to include limitations relating to a processor, operatively connected to the at least one transducer, and configured to process the recited first signals to determine the location

of the lumen of the blood vessel by comparing a region of reduced energy reflection within the tissue as compared with higher levels of energy reflection in surrounding tissue.

Voss does not teach or suggest comparing a region of reduced energy reflection as compared with higher levels of energy reflection in surrounding tissue. **In fact, Voss suggests quite the opposite.** Voss is looking for reflected ultrasonic waveforms in which the Doppler shift is at a maximum. By positioning the pressure sensor at a point where maximum blood flow is measured, the best pressure readings under the invention of Voss can be obtained as this closely correlates with being positioned most directly over the artery of interest.

Therefore, the invention of Claim 19 is concerned with regions of reduced energy reflection as these are indicative of the detection of lumen within blood arteries such as the radial artery, and not necessarily concerned with maximum Doppler shifted ultrasonic waves.

Hence, Applicant respectfully submits that Voss does not teach or suggest identifying a region of reduced energy reflection corresponding to a blood vessel, and therefore Claim 19 cannot be anticipated by Voss as a matter of law.

Claim 36 – Applicant respectfully disagrees with Examiner’s contention that Voss et al teaches or suggests “forming at least one integrated power representation to identify at least one region of reduced energy reflection within said tissue”, and traverses this rejection. Although both Voss and the invention of Claim 36 are concerned with the detection of the proximity of an artery (e.g., a radial artery), the Voss reference performs this task using a *completely different* processing method then that of the present invention. Specifically, Voss uses the scattered bursts of ultrasonic waves to compare frequencies and phase angles of the transmitted and returned bursts, monitoring the Doppler shift of the blood flowing within the arteries. It then monitors the magnitude of the comparison signal to determine the proximity of the ultrasonic transducer to the artery. No integration is discussed or implied in Voss that Applicant herein is aware of.

The invention of Claim 36 on the other hand utilizes an integrated power representation of the sensed acoustical energy reflection to locate the lumen of the blood vessel. No “comparison” of the type taught in Voss is performed. This data is obtained, *inter alia*, via the

Application No. : 09/815,982
Filed : March 22, 2001

use of a transverse sweep of ultrasonic energy into the surrounding tissue. Voss in no way teaches or suggests such analysis capability or integration; therefore, as a matter of law, Voss can not anticipate Claim 36.

Applicant therefore respectfully submits that Claim 36 distinguishes over the art of
5 record, and is in condition for allowance.

Claim 38 – While Applicant concedes that Voss discloses that the control of the ultrasound transducer and blood pressure sensor is coupled to a processor, Voss does not teach or suggest a computer program adapted to determine a power profile based on signals produced by a
10 signal converter as recited in Claim 38. There is no teaching or suggestion in Voss that Applicant can find regarding determining a power profile based on signals produced by a signal converter. **Applicant respectfully requests that the Examiner specifically point to and support his contention that Voss teaches such functionality.**

As Applicant contends that Voss does not teach or even remotely suggest, *inter alia*, a
15 computer program running on a digital processor adapted to determine a power profile based on signals produced by a signal converter, Voss cannot anticipate Claim 38.

Hence, Applicant respectfully submits that Claim 38 distinguishes over the art of record, and is in condition for allowance.

20 **Claim 45** – Applicant respectfully submits that Voss neither teaches nor remotely suggests the detection of a plateau in order to identify an area of reduced energy reflection corresponding to a blood vessel. As previously discussed, Voss merely teaches the use of scattered bursts of ultrasonic waves to compare frequencies and phase angles of the transmitted and returned bursts, in effect monitoring the Doppler shift of the blood flowing within the
25 arteries. Voss then teaches monitoring the magnitude of the comparison signal to determine the proximity of the ultrasonic transducer to the artery. It does not teach or suggest the affirmative detection of a plateau. Hence, as a matter of law, Voss cannot anticipate the invention of Claim

Application No. : 09/815,982
Filed : March 22, 2001

45, and Applicant therefore respectfully submits that Claim 45 distinguishes over the art of record and is in condition for allowance.

Claim 46 – Applicant has by this paper amended Claim 46 to include limitations relating to identifying at least one region of reduced energy reflection within said tissue as compared with higher levels of energy reflection in surrounding tissue. Support for this limitation is found at, *inter alia*, Page 36, lines 10-19 of the application as filed.

Voss does not teach nor remotely suggest “identifying at least one region of reduced energy reflection as compared with higher levels of energy reflection in surrounding tissue.” In fact, Voss suggests quite the opposite. Voss is looking for reflected ultrasonic waveforms in which the Doppler shift is at a maximum. By positioning the pressure sensor at a point where maximum blood flow is measured, the best pressure readings under the invention in Voss can be obtained as this closely correlates with being positioned most directly over the artery of interest.

Moreover, as previously discussed, Voss literally has no use for signals which do not generate a Doppler shift (i.e., those associated with tissue). The only time its “comparison” signals are significant is when a phase/frequency shift is present. **There is simply no evaluation of energy reflection associated with tissue.**

Therefore, while the invention of Claim 46 is concerned with regions of reduced energy reflection as these are indicative of the detection of lumen within blood arteries, such as the radial artery it is not necessarily concerned with maximum Doppler shifted ultrasonic waves. Hence, applicant respectfully submits that Voss does not teach or remotely suggest identifying a region of reduced energy reflection corresponding to a blood vessel, therefore Claim 46 is not anticipated by Voss and therefore should be in condition for allowance as currently amended.

Claim 49 – Applicant respectfully requests that the examiner specifically point to and provide support for examiners contention that Voss teaches or suggests either “developing an envelope squared representation of said baseband data” or “applying a depth-dependent gain to at least a portion of said envelope squared representation.” Applicant’s reading of Voss can not

Application No. : 09/815,982
Filed : March 22, 2001

find any support for this contention and therefore believes that Voss does not anticipate each and every limitation present in Claim 49. Hence, applicant respectfully requests that Claim 49 should be in condition for allowance as it can not be, as a matter of law, anticipated by Voss.

5 **Claim 51** – Applicant has amended Claim 51 to include limitations wherein “said determination of the location is indicative of both lateral position and depth.” Support for this limitation can be found, *inter alia*, at Page 36, lines 15-19 of the present application. For reasons similar to those previously discussed with respect to Claim 1 above, Applicant submits that Claim 51 as amended herein distinguishes over Voss and the other art of record, and is in
10 condition for allowance.

Claims 53, 56 and 58 – Applicant respectfully submits that Voss neither teaches nor even remotely suggests the limitation of locating at least one wall of a blood vessel. Applicant concedes that Voss is useful in helping to position a pressure transducer over a blood vessel
15 within a reasonable amount of accuracy for a number of applications; however Voss in no way teaches or suggests the ability to locate a vessel wall. Although perhaps the location of the vessel wall can be estimated by Voss’ method (e.g., by scientific or anecdotal evidence of estimated vessel diameter), the wall itself can not be located or measured with the invention of Voss (see also *inter alia*, Figures 21 and 22 of the present invention and accompanying discussion). **This is**
20 **particularly true since the wall of the artery has no Doppler component, and hence would generate no frequency or phase shift which the “comparison” circuitry of Voss could detect.**

 As Voss does not teach or suggest locating at least one wall of a blood vessel, it can not anticipate the inventions of Claims 53, 56 or 58.

25 Therefore applicant respectfully submits that these claims and all claims depending directly or indirectly therefrom are in condition for allowance.

§103 Rejections

Application No. : 09/815,982
Filed : March 22, 2001

With respect to the Examiner's Section 103 rejections of various claims as set forth in pars. 4-6 of the Office Action, Applicant respectfully traverses these rejections in their entirety. Applicant disagrees with the Examiner's contention that although Voss does not explicitly state measuring depths, normalizing power function, analyzing the blood vessel as function of lumen position, etc. that it is somehow inherently achieved because Voss' compression control and maximum and minimum pressure normalization to detect the vessel is "equivalent" to the above mentioned characteristics (see top of page 4 of the Office Action). Applicant respectfully believes this contention is completely without merit.

Voss, simply stated, does not measure depth, etc. because it is a "dumb" system designed only to look for a signal maximum associated with moving blood (as previously discussed). Such search for a maximum requires none of the innate calculations or "intelligence" present in Applicant's claimed inventions. **For example, in the context of Claim 54, how would using the "received reflected energy" to form A-mode signals, and compute an integrated power by summing consecutive samples of the square of the envelope of the A-mode signals in first direction, be inherent in the teachings of Voss, when Voss in no way teaches or suggests (i) integration, (ii) summing of consecutive samples, or (iii) the square of the envelope?** The simple answer is that it would and could not. Such aspects are not explicitly taught nor are they in any way inherent in Voss, since Voss is only concerned with moving blood cell detection.

Furthermore, having the capability to measure the signal level of the ultrasonic reflections as a function of depth can provide the added functionality of e.g., being able to determine blood vessel size, location in three dimensions, etc. Voss' compression and pressure normalization disclosures could never have such functionality absent the claimed aspects of the present invention, which are nowhere taught in Voss. How, for example, would one inherently determine vessel position in multiple dimensions without measuring its depth? Voss teaches nothing of depth measurement.

Further, as applicant believes that it has overcome the Examiner's rejections as it applies to the independent claim rejections under 35 U.S.C. 102(e) above. All of the above mentioned dependent claims either depend directly or indirectly from these rejected base claims and thus the

Application No. : 09/815,982
Filed : March 22, 2001

35 U.S.C. 103(a) rejections on pages 3-4 of the Office Action are further rendered moot. Applicant therefore respectfully submits that these dependent claims are in condition for allowance as well.

5 *Other Remarks*

Applicant hereby specifically reserves the right to prosecute claims of different or broader scope in a continuation or divisional application, as well as all rights of appeal.

Applicant notes that any claim cancellations or additions made herein are made solely for the purposes of more clearly and particularly describing and claiming the invention and responding to the aforementioned restriction election, and not for purposes of overcoming art or for patentability. The Examiner should infer no (i) adoption of a position with respect to patentability, (ii) change in the Applicant's position with respect to any claim or subject matter of the invention, or (iii) acquiescence in any way to any position taken by the Examiner, based on such cancellations or additions.

Furthermore, any remarks made with respect to a given claim or claims are limited solely to such claim or claims.

If the Examiner has any questions or comments that may be resolved over the telephone, he/she is requested to call the undersigned at (858) 675-1670.

Respectfully submitted,

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